K042777 1/2

DEC - 1 2004

Harmonic ACE™ Curved Shears
510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Kimberly Shoemaker
Manager, Regulatory Affairs

Date Prepared:
October 4, 2004

Name of Device
Trade Name: Harmonic ACE™ Curved Shears with Hand Control
Classification Name: Electrosurgical Cutting and Coagulation Device

Predicate Devices:
UltraCision® Harmonic Scalpel® Curved Shears (LCS) cleared under K993054 on 12/09/1999 and UltraCision® Harmonic Scalpel® Hand Switching Adaptor cleared under K002906 on 12/15/2000

Device Description
The Harmonic ACE™ Curved Shears with Hand Control is a sterile, single patient use instrument consisting of a pistol grip housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level) on both sides of the grip housing. The grip housing has an integrated audible/tactile mechanism for indicating full trigger closure. The instrument has a rotating shaft with a curved blade and clamp arm and is designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instrument is available in 23 cm and 36 cm lengths with a shaft diameter of 5.5 mm and a 15 mm active blade length.

Indications for Use
The Harmonic ACE™ Curved Shears with Hand Control is indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, pediatric, gynecologic, urologic and other open and endoscopic procedures.

Technological Characteristics
The Harmonic ACE™ is similar to the predicate devices with respect to design and intended use.

Performance Data
Bench testing and pre-clinical laboratory evaluations were performed to demonstrate that the device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

Ms. Kimberly Shoemaker
Manager, Regulatory Affairs
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K042777
Trade/Device Name: Harmonic ACE™ Curved Shears with Hand Control
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 5, 2004
Received: October 6, 2004

Dear Ms. Shoemaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042777

Device Name: Harmonic ACE™ Curved Shears with Hand Control

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042777